

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60

DOCKET NUMBER	ANTICIPATED CLASSIFICATION		PRIOR APPLICATION EXAMINER	ART UNIT
105336.124DIV	CLASS 548	SUBCLASS 491,516	M. Bucknam	1202

Assistant Commissioner for Patents
WASHINGTON, DC 20231

ATTENTION BOX PATENT APPLICATION

This is a request for filing a ☐ Continuation ☒ Divisional application under 37 C.F.R. § 1.60 of pending prior application Serial No. 08/624,508 filed on April 5, 1996 entitled "Nitric Esters Having Anti-Inflammatory and/or Analgesic Activity and Process for Their Preparation."

1. Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 08/624,508, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS	9 - 20		x \$ 22 =	\$
	INDEPENDENT CLAIMS	1 - 3		x \$ 80 =	
	MULTIPLE DEPENDENT CLAIMS (if applicable)			+ \$260 =	
				BASIC FEE	\$ 770.00
				TOTAL OF ABOVE CALCULATIONS =	
	Reduction by 50% for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28).				
				TOTAL =	\$ 770.00

2. ☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27
☐ is enclosed.
☐ was filed in prior application number / and such status is still proper and desired (37 CFR 1.28(a)).
3. ☒ The Commissioner is hereby authorized to share any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 08-0219. A duplicate copy of this sheet is enclosed.
4. ☒ A check in the amount of \$ 770.00 is enclosed.
5. ☒ Cancel in this application original claims 3-8, and 24-30 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)


EXPRESS MAIL LABEL NO. Em50462554405
DATE OF DEPOSIT July 29, 1997

REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, PAGE 2

6. ☒ The inventor(s) of the invention being claimed in this application is (are): Piero Del Soldato
7. ☐ This application is being filed by less than all the inventors named in the prior application. In accordance with 37 CFR 1.60(b), the Commissioner is requested to delete the name(s) of the following person or persons who are not inventors of the invention being claimed in this application:
8. ☒ Amend the specification by inserting before the first line the sentence: "This application is a ☐ continuation ☒ division of application number 08/624,508, filed April 5, 1996, pending and allowed."
9. ☐ New formal drawings are enclosed.
10. ☒ Priority of foreign application number PCT/EP94/03182, filed on September 23, 1994, claiming priority to MI 94 A 000916, filed on May 10, 1994, in Italy and 9320599.5, filed on October 6, 1993 in Great Britain is claimed under 35 U.S.C. 119(a) - (d).
11. ☐ A preliminary amendment is enclosed.
12. ☒ The prior application is assigned of record to NICOX S.A.
45 Avenue Kleber
75116 Paris, France
13. ☐ Also enclosed:
14. ☒ The power of attorney in the prior application is to at least one of the following: Hollie L. Baker, Reg. No. 31,321; Michael Bevilacqua, Reg. No. 31,091; Michael A. Diener, Reg. No. 37,122; Richard Goldenberg, Reg. No. 38,985; Wayne M. Kennard, Reg. No. 30,271; Wayne A. Keown, Reg. No. 33,923; Ann-Louise Kerner, Reg. No. 33,523; James B. Lampert, Reg. No. 24,564; Gretchen Rice, Reg. No. 37,429; Donald R. Steinberg, Reg. No. 37,241; Colleen Superko, Reg. No. 39,850; Henry N. Wixon, Reg. No. 32,073.
- a. ☒ The power of attorney appears in the original papers in the prior application.
- b. ☐ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
- c. ☐ Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.)
15. ☒ Please address all correspondence and facsimiles to:

HALE AND DORR LLP
1455 Pennsylvania Avenue, N.W.
Washington, DC 20004-1008
Tel.: (202) 942-8400
Fax: (202) 942-8484

29 July 1997
Date


Signature
Hollie L. Baker
Typed or printed name

- ☐ Inventor(s)
- ☐ Assignee of complete interest. Certification under 37 CFR 3.73(b) is enclosed.
- ☒ Attorney or agent of record
- ☐ Filed under 37 CFR 1.34(a)
Registration number if acting under 37 CFR 1.34(a).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60

DOCKET NUMBER	ANTICIPATED CLASSIFICATION		PRIOR APPLICATION EXAMINER	ART UNIT
105336.124DIV	CLASS 548	SUBCLASS 491,516	M. Bucknam	1202

Assistant Commissioner for Patents
 WASHINGTON, DC 20231

ATTENTION BOX PATENT APPLICATION

This is a request for filing a ☐ Continuation ☒ Divisional application under 37 C.F.R. § 1.60 of pending prior application Serial No. 08/624,508 filed on April 5, 1996 entitled "Nitric Esters Having Anti-Inflammatory and/or Analgesic Activity and Process for Their Preparation."

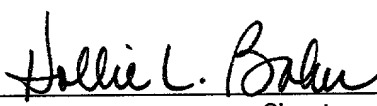
1. Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 08/624,508, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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☐ is enclosed.
☐ was filed in prior application number / and such status is still proper and desired (37 CFR 1.28(a)).
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EXPRESS MAIL LABEL NO. EM50462554405
 DATE OF DEPOSIT July 29, 1997

REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, PAGE 2

6. ☒ The inventor(s) of the invention being claimed in this application is (are): Piero Del Soldato
7. ☐ This application is being filed by less than all the inventors named in the prior application. In accordance with 37 CFR 1.60(b), the Commissioner is requested to delete the name(s) of the following person or persons who are not inventors of the invention being claimed in this application:
8. ☒ Amend the specification by inserting before the first line the sentence: "This application is a ☐ continuation ☒ division of application number 08/624,508, filed April 5, 1996, pending and allowed."
9. ☐ New formal drawings are enclosed.
10. ☒ Priority of foreign application number PCT/EP94/03182, filed on September 23, 1994, claiming priority to MI 94 A 000916, filed on May 10, 1994, in Italy and 9320599.5, filed on October 6, 1993 in Great Britain is claimed under 35 U.S.C. 119(a) - (d).
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45 Avenue Kleber
75116 Paris, France
13. ☐ Also enclosed:
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Washington, DC 20004-1008
Tel.: (202) 942-8400
Fax: (202) 942-8484
- 29 July 1997
Date
- 
Signature
Hollie L. Baker
Typed or printed name
- ☐ Inventor(s)
☐ Assignee of complete interest. Certification under 37 CFR 3.73(b) is enclosed.
☒ Attorney or agent of record
☐ Filed under 37 CFR 1.34(a)
Registration number if acting under 37 CFR 1.34(a).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Del Soldato, Piero
Serial No.: To Be Assigned
(Divisional Application of 08/624,508)
Filed: (Herewith)
For: Nitric Esters Having Anti-Inflammatory And/Or Analgesic
Activity and Process for Their Preparation
Examiner: M. Bucknum
Art Unit: 1202
Attorney Docket No.: 105336.124DIV

Preliminary Amendment for Divisional Application

Assistant Commissioner for Patents
Washington D.C. 20231

Dear Sir:

Prior to examination of the claims being filed for this divisional filing, the following amendments are requested to be made.

Please amend the application as follows:

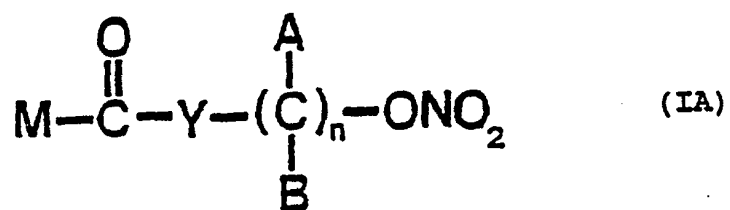
IN THE SPECIFICATION:

Please insert at the end of the specification the attached "Abstract of the Invention."

IN THE CLAIMS:

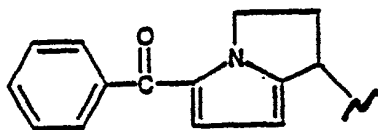
1. (Once Amended) Derivatives of propionic acid, 1-(p-chlorobenzoyl)-5-methoxy-2-methyl-3-indolylacetic acid, 5-benzoyl-1,2-dihydro-3H-pyrrolo[1,2-a]pyrrole-1-carboxylic acid, 6-methoxy-2-naphthylacetic acid, characterized in that they have the

following general formula:

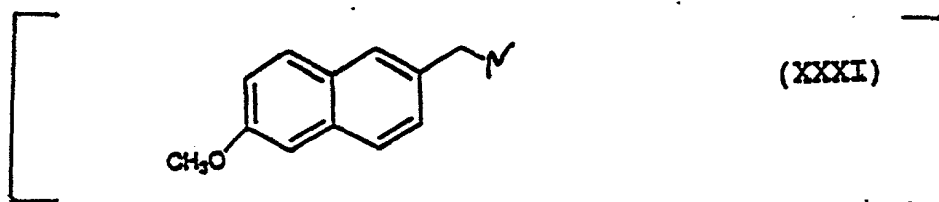


where:

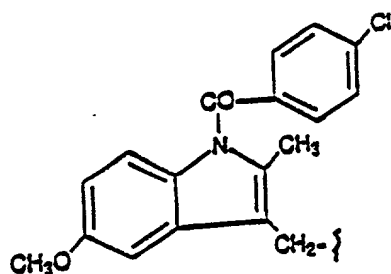
A and B are chosen from [among] hydrogen, linear or branched, substituted or non substituted alkyl chains, M is chosen from [among]:



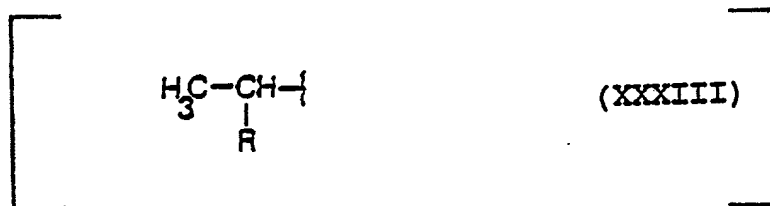
(XXX)



(XXXI)

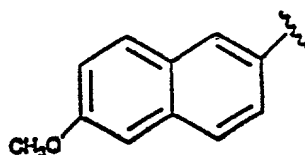


(XXXII)

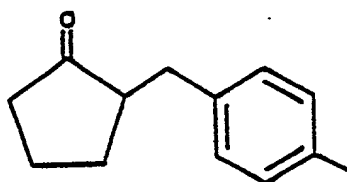


(XXXIII)

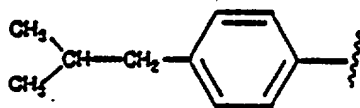
where R is chosen from [among]:



(II)



(X)



(III)

Y is chosen among oxygen, NH, NR₁, where R₁ is a linear or branched alkyl group, and n is an integer from [comprised between] 1 and 10.

Remarks

Claims 1-2, 9-10 and 19-23 are currently pending in this divisional application. Claim 1 has been amended to conform the claim to the election of Group I, drawn to a compound, composition and method of use, when the compound is structural formula (XXX) and (XXXII), containing pyrrolo[1,2a]pyrrolyl and indolyl rings, respectively. The other amendments to Claim 1 is to correct minor terminology.

Respectfully submitted,



Hollie L. Baker
Registration No. 31,321

Date: 29 July 1997

Hale and Dorr LLP
1455 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 942-8400 telephone
(202) 942-8484 facsimile

/netuser12/baker/op/sama/105336.124/divpramd.wpf

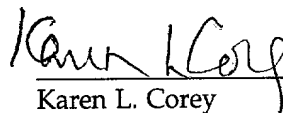


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Del Soldato, Piero
Serial No.: To Be Assigned
(Divisional Application of 08/624,508)
Filed: (Herewith)
For: Nitric Esters Having Anti-Inflammatory And/Or Analgesic
Activity and Process for Their Preparation
Examiner: M. Bucknum
Art Unit: 1202
Attorney Docket No.: 105336.124DIV

CERTIFICATE OF MAILING UNDER 37 CFR §1.10

I hereby certify that this correspondence and the enclosures referenced herein are being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" (Express Mail Label No. EM504625544US with sufficient postage in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on July 29, 1997.


Karen L. Corey

TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

ATTENTION BOX PATENT APPLICATION

Sir:

Enclosed for filing is a divisional patent application including the following:

1. Request for Filing a Divisional Patent Application Under 37 CFR 1.60;
2. Copy of prior application no. 08/624,508 consisting of:
27 pages of specification, and
14 pages of claims;
3. Copy of Declaration for Patent Application filed in prior application;

EXPRESS MAIL LABEL NO. EM504625544 US
DATE OF DEPOSIT July 29, 1997

Applicant: Del Soldato, Piero
Serial No.: To Be Assigned
(Divisional Application of 08/624,508)
Atty Docket: 105336.124DIV
Page 2

4. Copy of Power of Attorney From Assignee filed in prior application;
5. Copy of Assignment filed in prior application;
7. Copy of Preliminary Amendment filed in prior application;
8. Preliminary Amendment for Divisional Application with Abstract;
9. Information Disclosure Statement with references cited;
10. Hale and Dorr Check No. 35206 for \$770.00; and
11. Stamped, self-addressed postcard.

Respectfully submitted,

HALE AND DORR LLP

By: Hollie L. Baker
Hollie L. Baker
Attorney for Applicant
Registration No. 31,321

Date: July 29, 1997

Hale and Dorr LLP
1455 Pennsylvania Avenue, N.W.
Washington, DC 20004
(617) 526-6000 (telephone)
(617) 526-5000 (facsimile)

/netuser6/karenc/baker/sama/105336.124/div/divptolt.wpf

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: DEL SOLDATO, Piero

Serial No.: To Be Assigned
(U.S. National Phase of PCT/EP94/03182)

Filed: Concurrently Herewith

For: NITRIC ESTERS HAVING ANTI-INFLAMMATORY AND/OR
ANALGESIC ACTIVITY AND PROCESS FOR THEIR
PREPARATION

Attorney Docket No.: 105336.124

PRELIMINARY AMENDMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Prior to the examination of the above-identified application and the calculation of the filing fee, Applicants submit the following amendments to the claims:

IN THE CLAIMS:

On page 28, line 1, please delete "CLAIMS" and insert instead thereof -- What Is Claimed Is: --.

Please delete claims 11-18.

Please add the following new claims 19-30:

19. A pharmaceutical composition comprising at least one nitric acid compound as claimed in claim 1 and a pharmaceutical acceptable carrier.

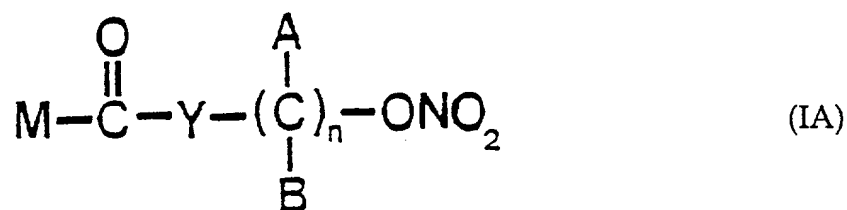
20. The pharmaceutical composition of claim 19, wherein said composition has anti-inflammatory activity.

21. The pharmaceutical composition of claim 19, wherein said composition has analgesic activity.

22. The pharmaceutical composition of claim 19, wherein said composition is used in the treatment of rheumatic diseases, immunological disorders, and moderate to medium painful conditions.

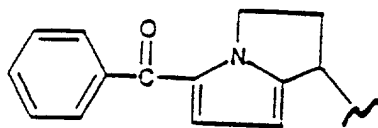
23. The composition of claim 19, wherein said composition is used in the treatment of diseases affecting the cardiovascular system, senile dementia, myocardial and brain ischemia, and arterial thrombosis.

24. A process for the preparation of nitric esters according to claim 1 and having the following general formula:

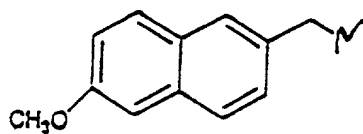


where A and B are chosen among hydrogen, linear or branched, substituted or non substituted alkyl chains,

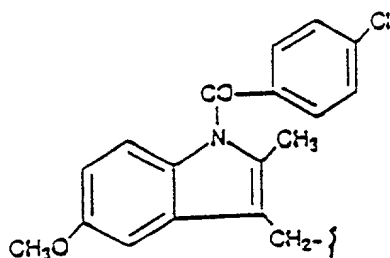
where M is chosen among:



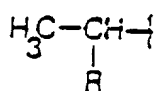
(XXX)



(XXXI)

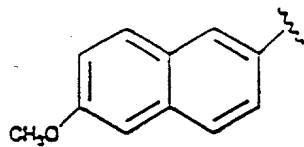


(XXXII)

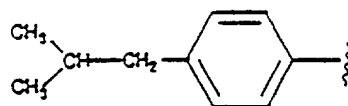


(XXXIII)

where R is chosen among:



(II)



(III)

(X)

Y is chosen among oxygen, NH, NR₁, where R₁ is a linear or branched alkyl group, and n is comprised between 1 and 10,

comprising the following steps:

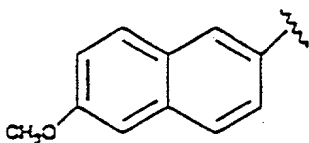
(a) contacting a sodium salt of derivatives having the following general formula:



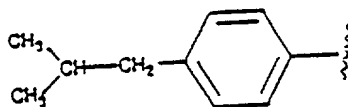
where M is chosen among the following structures: (XXX), (XXXI), (XXXII),



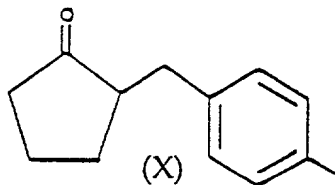
where R is chosen among the following structures:



(II)

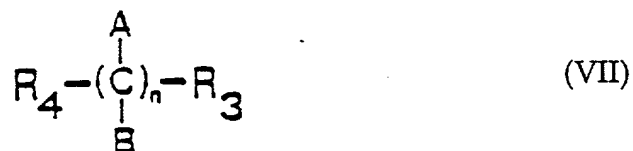


(III)



or contacting derivatives of structure (VIA) functionalized to the carboxylic group;

(b) reacting the sodium salt of said derivatives (VIA) or of said derivatives (VIA) functionalized to the carboxylic group, with a compound having the following general formula:



where:

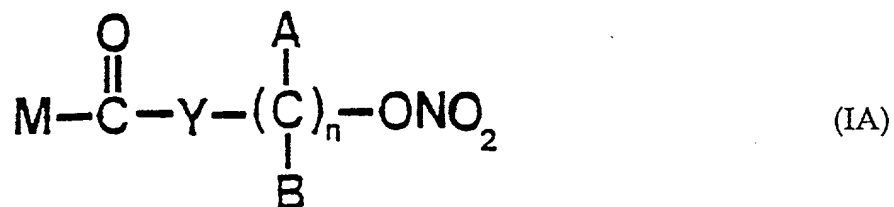
R_4 is chosen among chlorine, bromine, NHR_5 with R_5 hydrogen, linear or branched alkyl chain, A and B are chosen among hydrogen, linear or branched, substituted or non substituted alkyl chains, R_3 is chosen among chlorine, bromine and iodine, and n is comprised between 1 and 10, to produce monomeric esters or amides; and

(c) reacting said monomeric esters or said amides with a nitrating agent to produce the nitric esters of derivatives (IA).

25. The process of claim 24, wherein said carboxylic group is an acyclic chloride or anhydride chloride.

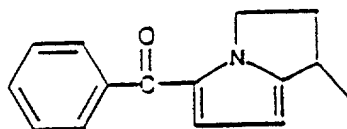
26. The process of claim 24, wherein said nitrating agent is AgNO_3 .

27. A process for the preparation of nitric esters according to claim 1 and having the following general formula:

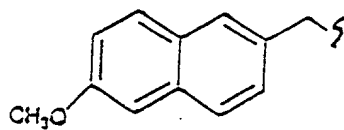


where A and B are chosen among hydrogen, linear or branched, substituted or non substituted alkyl chains,

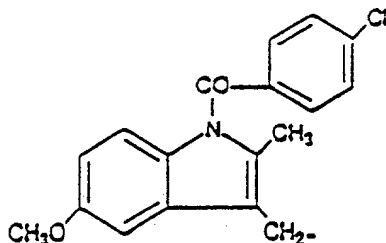
M is chose among



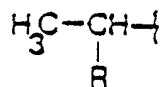
(XXX)



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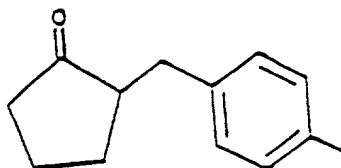


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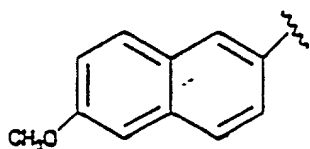


(XXXIII)

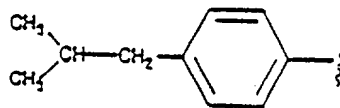
where R is chosen among:



(X)



(II)

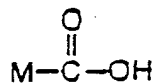


(III)

Y is chosen among oxygen, NH, NR₁, where R₁ is a linear or branched alkyl group, and n is comprised between 1 and 10,

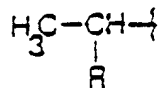
comprising the following steps:

(a) contacting a sodium salt of derivatives having the following general formula:



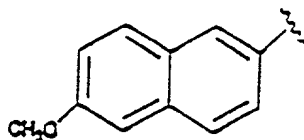
(VIA)

where M is chosen among the following structures: (XXX), (XXXI), (XXXII),

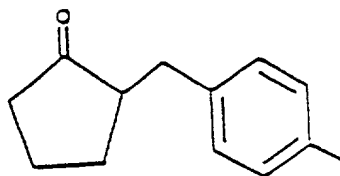


(XXXIII)

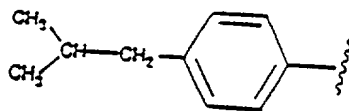
where R is chosen among the following structures:



(II)



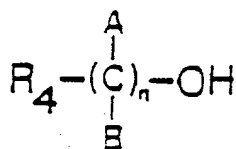
(X)



(III)

or contacting derivatives of structure (VIA) functionalized to the carboxylic group;

(b) reacting the sodium salt of said derivatives (VIA) or of said derivatives (VIA) functionalized to the carboxylic group, with a composition having the following general formula:



(VIII)

where:

R₄ is chosen among chlorine, bromine, NHR₅ with R₅ hydrogen, linear or branched alkyl chain, A and B are chosen among hydrogen, linear or branched, substituted or non substituted alkyl chains, and n is comprised between 1 and 10, to produce monomeric esters or amides;

(c) reacting said monomeric esters or said amides with an halogenating compound, to produce said monomeric esters or said amides, characterized by the presence of a terminal halogen group; and

(d) reacting said monomeric esters or said amides, characterized by the presence of a terminal halogen group, with a nitrating agent, to produce nitric esters of derivatives (IA).

28. The process of claim 27, wherein said carboxylic group is an acyclic chloride or anhydride chloride.

29. The process of claim 27, wherein said halogenating compound is PBr₃.

30. The process of claim 27, wherein said nitrating agent is AgNO₃.


REMARKS

This Preliminary Amendment is being submitted to make the claims conform to standard U.S. practice. The pending claims are 1-10 and 19-30. No new matter has been

added with these claims. Support for the newly submitted claims 19-30 can be found in the original claims 1 to 18, and throughout the specification.

If there are any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,



Hollie L. Baker
Registration No. 31,321

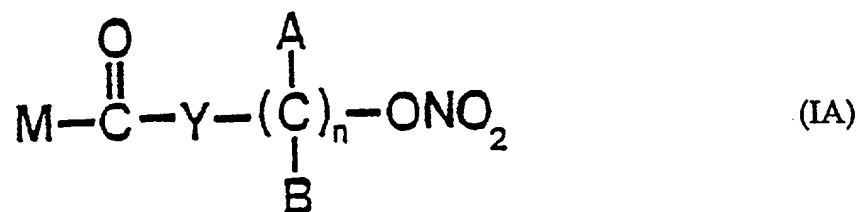
Date: 4 April 1996

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ABSTRACT OF THE INVENTION

This invention is directed to nitric esters of derivatives of propionic acid, 1-(p-chlorobenzoyl)-5-methoxy-2-methyl-3-indolylacetic acid, 5-benzoyl-1,2-dihydro-3H-pyrrolo[1,2-a]pyrrole-1-carboxylic acid, 6-methoxy-2-naphthylacetic acid, characterized in that they have the following general formula:



These nitric ester derivatives may be formulated into pharmaceutical compositions and administered for their anti-inflammatory and/or analgesic activity.

1 + 2 = 3

[illegible]

I hereby claim the benefit under Title 35, United States code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
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(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
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(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
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The undersigned hereby grant(s) Hollie L. Baker, Esquire, Reg. No. 31,321; Henry N. Wixon, Esq., Reg. No. 32,073; William J. Healey, Esq., Reg. No. 36,760; Judith A. Evans, Esq., Reg. No. 38,874; James B. Lampert, Esq., Reg. No. 24,564; Michael J. Bevilacqua, Esq., Reg. No. 31,091; Wayne M. Kennard, Esq., Reg. No. 30,271; Donald R. Steinberg, Esq., Reg. No. 37,241 and Michael A. Diener, Esq., Reg. No. 37,122 of HALE and DORR, 1455 Pennsylvania Avenue, N.W., Washington, D.C. 20004, power to insert on this Declaration any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: PIERO DEL SOLDATO

Piero Del Soldato

Inventor's signature

March 14, 1996

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POWER OF ATTORNEY
FROM ASSIGNEE

NICOX S.A., whose
principal address is: 45 Avenue Kléber - 75116 PARIS, France, is Assignee of the
entire right, title and interest for the United States of America (as defined in 35 U.S.C. § 100), of an invention
known "Nitric esters having anti-inflammatory and/or analgesic activity" (Attorney
and process for their preparation)
Docket No. _____ which is disclosed and claimed in a patent application of the same title by
reason of an Assignment to the Assignee executed on by the inventor(s) Piero Dal Soldato
said application filed on _____ at the U.S. Patent and Trademark Office, having Serial No.
_____).

The Assignee hereby appoints the following U.S. attorneys to prosecute this application and any division,
continuation-in-part, or reissue applications thereof, and to transact all business in the Patent and Trademark
Office connected therewith: Hollie L. Baker, Reg. No. 31,321; Henry N. Wixon, Reg. No. 32,073; William J.
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Steinberg, Esq., Reg. No. 37,241 and Michael A. Diener, Esq., Reg. No. 37,122. The undersigned hereby
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For:

NICOX S.A.

By:

Michele Garufi

Title:

President

Date:

March 14, 1996